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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,100	12/28/2001	Erik Ho Fong Wong	00378.US1	1691
25533	7590	12/15/2004	EXAMINER	
PHARMACIA & UPJOHN 301 HENRIETTA ST 0228-32-LAW KALAMAZOO, MI 49007			SPIVACK, PHYLLIS G	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,100

Applicant(s)

ERIK HO FONG WONG ET AL.

Examiner

Phyllis G. Spivack

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,7-9,11-13,15,16,18 and 23-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7-9,11-13,15,16 and 23-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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A Request for Continued Examination (RCE) filed September 29, 2004 is acknowledged and accepted. Claims 2, 5, 6, 10, 14, 17 and 19-22 are canceled. New claims 23-25 are presented. Accordingly, claims 1, 3, 4, 7-9, 11-13, 15, 16, 18 and 23-25 are now under consideration.

In the last Office Action claims 1, 3, 4, 7-9, 11-13, 15-16 and 18 were rejected under 35 U.S.C. 103 as being unpatentable over Bymaster et al., EP 0830864. It was asserted Bymaster teaches combination compositions comprising an atypical antipsychotic agent and a serotonin reuptake inhibitor for treatment of schizophrenia.

Reboxetine is not a serotonin reuptake inhibitor. This rejection of record under 35 U.S.C. 103 is withdrawn.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 4, 7-9, 11-13, 15, 16 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koch et al., Eur. J. Clin. Pharmacol. (abstract).

Koch teaches the administration of the norepinephrine reuptake inhibitor reboxetine with the neuroleptic agent olanzapine in the treatment of psychotic depression. The claims differ in that Koch discloses a polypragmatic treatment wherein multiple drugs, in addition to reboxetine and olanzapine, are simultaneously administered. However, the open language of the present claims allows for the addition of any number of other active agents in the composition. The intended use of

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composition claims confers no patentable weight to the claims. *In re Hake*, 114 USPQ 161. Olanzapine, clozapine and risperidone are well established in the psychiatry art for use in the treatment of schizophrenia. Reboxetine is established in the prior art as a safe and effective antidepressant that is substantially effective in combination therapy. One skilled in the art would have been motivated to combine reboxetine with neuroleptic agents, such as olanzapine, clozapine or risperidone, in view of Koch's polytherapeutic approach to treating depression and therapeutic regimens that are well known in the psychiatric art. Such would have been obvious in the absence of evidence to the contrary because depression is a common finding in the schizoid disease process. The determination of an optimal optical isomer of reboxetine, modes of administration, dosages, dosing regimens and a delivery vehicle are parameters well within the purview of those skilled in the art through no more than routine experimentation.

Claim 18 appears to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Phyllis G. Spivack whose telephone number is 571-272-0585. The examiner can normally be reached Monday to Friday from 10:30 to 7 PM.

If attempts to reach the Examiner by telephone are unsuccessful after one business day, the Examiner's supervisor, Chris Low, can be reached by phone at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).



Phyllis G. Spivack
Primary Examiner
Art Unit 1614

PHYLLIS SPIVACK
PRIMARY EXAMINER

December 10, 2004